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JUL 24 2000

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,997,841

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,997,841, which claims the human drug product AMERGE® (naratriptan hydrochloride) and the method of use of AMERGE®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 694 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 694 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 29, 1999 (64 Fed. Reg. 23086). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (519) + 434 \\ &= 694 \text{ days}\end{aligned}$$

Since the regulatory review period began July 5, 1995, after the patent issue date (March 5, 1991), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the five year limitation of 35 U.S.C. § 156(g)(6)(A) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

| | | |
|--------------------------|---|-----------------------------|
| U.S. Patent No. | : | 4,997,841 |
| Granted | : | March 5, 1991 |
| Original Expiration Date | : | August 12, 2008 |
| Applicant | : | Alexander W. Oxford, et al. |
| Owner of Record | : | Glaxo Wellcome Inc. |
| Title | : | Indole Derivatives |

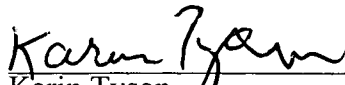
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|------------------------------|---|-------------------------------------|
| Classification | : | 514/323 |
| Product Trade Name | : | AMERGE® (naratriptan hydrochloride) |
| Term Extended | : | 694 days |
| Expiration Date of Extension | : | July 7, 2010 |

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916 or (703) 872-9411
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

| | | |
|-----|---|---|
| cc: | David T. Read | RE: AMERGE® (naratriptan hydrochloride) |
| | Acting Director Regulatory Policy Staff, CDER | FDA Docket No.: 95E-0614 |
| | Food and Drug Administration | |
| | 1451 Rockville Pike, HFD-7 | |
| | Rockville, MD 20852 | |